

### REMARKS

#### Rejection of claims under 35 U.S.C. 112:

Claims 16, 17 and 19 have been rejected on page 3 of the Office Action. Applicants have canceled claims 16 and 17 in this Response and have previously canceled claim 19. Therefore, the rejection appears to be obviated.

#### Rejection of claims under 35 U.S.C. 102:

Applicants gratefully acknowledge the withdrawal of the *Isner et al.* and *Wolff et al.* prior art references.

Claims 1, 2, 4-6, 12-14, 16-18, and 20 are rejected under §102(e) as being anticipated by Mann *et al.*


Applicants have submitted a further §131 Declaration stating that their processes were performed prior to the cited Mann *et al.* prior art. On page 5, an objection to the previous Wolff Declaration states that the process was performed in a different organ. Applicants hereby state that even though they are injecting into a heart vessel, the process performed is the same process as performed for delivery to the liver. Applicants also state that hydrostatic pressure was utilized in the prior performed process to deliver nucleic acids.

The objection to clamping refers to only one of the prior Declaration examples. In fact, the rest of the submitted examples use no clamping. Therefore, the process is not more invasive than the present process used on the heart.

Applicants submit that the notebook pages previously entered by the Wolff Declaration utilize a process that is far more closely associated with the present heart delivery methods than anything taught, described, or implied by the Mann *et al.* cited art.

The Examiner's objections and rejections are now believed to be overcome by this response to the Office Action. In view of Applicants' amendments and discussion, it is submitted that claims 1, 2, 4-6, 12-14, 16-18, and 20 should be allowable and Applicants respectfully request an early notice to such effect.

Respectfully submitted,

  
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I hereby certify that this correspondence is being sent by facsimile transmission to the CMI Fax Center at 703.308.4242 addressed to: Assistant Commissioner for Patents, Washington, DC 20231 on Friday, August 01 2003.

  
Signature

Application of: **Hans Herweijer,** )  
**Jon A. Wolff, Larry F. Whitesell and** )  
**Matthew R. Wolff** )  
 Serial No.: 09/330,909 )  
 Filed: 6/11/99 )  
 Examiner: **J. Wolfach** )  
 Group Art Unit: 1632 )

For: A Process For Delivering Nucleic Acids To Cardiac Tissue

**DECLARATION UNDER 37 C.F.R. §1.131**

Commissioner for Patents  
 P.O. Box 1450  
 Alexandria, VA 22313-1450

Dear Sir:

I, Hans Herweijer, an inventor, hereby declare as follows:

1. I am an inventor of the captioned application.
2. It is known to me that the process performed in my specification, increased permeability in the form of increased pressure as described, was performed in Jon Wolff's (inventor) laboratory prior to the date of the cited Mann *et al.* patent application filing date.
3. It is known to me that the results from that testing indicate expression in extravascular cells (cells from outside the vessel).

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Hans Herweijer 8/1/03  
 Hans Herweijer Date